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Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 38th Year of Publication

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Conferences:

Lab Leadership Summit: Designing, Implementing & Managing a High-Profit Lab Outreach Program
May 11, 2017 – 8 a.m.-5 p.m.
Holiday Inn Airport South, Atlanta, GA
www.lableadershipsummit.com

Theranos Announces Settlement Agreements with CMS and Arizona Attorney General

After facing federal and state government scrutiny for more than a year, Theranos has reached agreements with the Centers for Medicare & Medicaid Services (CMS) and the Arizona Attorney General to alleviate some of its legal woes.

Global Settlement with CMS

April 17, Theranos announced it had "reached a global settlement agreement with the Centers for Medicare & Medicaid Services (CMS) that resolves all outstanding legal and regulatory proceedings between CMS and Theranos."

Continued on page 2

FDA Reports "Significant Progress" in Diagnostics Development

The U.S. Food and Drug Administration (FDA) recently unveiled its FY 2015-2016: Regulatory Science Progress Report. The report, the second of its kind under the Food and Drug Administration Safety and Innovation Act, says the agency has made "significant progress" in advancing the science of medical product development and evaluation, improving clinical evaluation, ensuring the safety and effectiveness of marketed products, and infrastructure/organizational development to advance regulatory science.

"FDA's regulatory responsibility to evaluate medical products drives our research agenda, but the outcomes of this research also directly foster and stimulate new medical product development," writes the agency in the report.

Improving Evaluation

The agency reports it has refined predictive models to support product evaluation by developing computational tools that now support nonclinical evaluation of medical products. Importantly for the diagnostic industry, the FDA says it has carefully designed a pathway to foster biomarker development and adoption. Over this review period, the FDA reports it qualified three new biomarkers for use in clinical trials through the Biomarker Qualification Program.

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Theranos Announces Settlement Agreements with CMS and Arizona Attorney General, *from page 1*

Last summer CMS had announced it would be issuing sanctions resulting from an inspection at Theranos' Newark, Calif. laboratory, revoking the CLIA operating certification, and barring Medicare payments for hematology and laboratory services at the facility. CMS also could have imposed $10,000 per day in penalties until the deficiencies cited in the inspection report were corrected.

Under the terms of the current agreement, however, those sanctions won't be imposed. Instead, CMS and Theranos have agreed:

- Theranos will not own or operate a clinical lab "within the next two years."
- Theranos will withdraw its appeal of CMS' sanctions against its Newark, Calif. laboratory.
- CMS withdraws its revocation of Theranos' CLIA certificates.
- CMS drops the civil monetary penalties imposed on Theranos to $30,000.

Last October, Theranos issued a statement that it would be closing its clinical laboratory operations and wellness centers and was committed to developing its miniaturized, automated testing platforms, such as the miniLab which founder Elizabeth Holmes had unveiled at the American Association for Clinical Chemistry annual meeting last August. In announcing this resolution of the CMS inspection issues, the company indicated it "looks forward to working with regulatory authorities to secure approval for these innovative technologies."

Restitution for Arizona Customers

One day after announcing the global settlement with CMS, Theranos issued a statement that it had reached agreement with the Arizona Attorney General's Office (AGO) avoiding potential consumer fraud litigation. Just a few months ago, the AGO issued a request for proposal signaling potential state consumer fraud lawsuits against Theranos related to its lab testing services. The AGO indicated in its request that it was initiating a lawsuit against Theranos and its subsidiaries alleging violations of the Arizona Consumer Fraud Act for representations related to its blood testing equipment and its Wellness Centers.

Theranos explained that under the terms of the settlement agreement with the AGO the company "will reimburse Arizona residents for all amounts they paid for Theranos blood testing services between 2013 and 2016." That amount totals $4.65 million. Payments will be made regardless of whether the customer's tests were among those voided or corrected and whether Theranos received payment for the tests. Theranos makes no admission of liability, however. In its statement regarding the settlement the company expressed a "commitment to resolving the issue amicably on behalf of Arizonans and working collaboratively with state officials."

Takeaway: Theranos resolves legal threats hanging over the company as it pursues its commitment to focusing on developing testing technologies, rather than operating clinical labs.

NIR

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ACA Credited with Growth in Preventive Screenings

While efforts to replace the Affordable Care Act (ACA) continue despite the initial failure to pass the American Health Care Act, there has been some indication that the ACA has led to more individuals getting preventive screening tests. Yet cancer-screening rates in the United States remain below Healthy People 2020 goals.

According to a March 2017 data brief from the National Center for Health Statistics (NCHS), more people received screenings to prevent cancer and heart disease in 2015 than in 2012, although the growth in screening was not consistent.

The ACA was intended to improve access to health care through both greater numbers of insured and coverage of "essential health benefits" (certain clinical preventive services) without copayments.

"The Affordable Care Act has helped to reduce such barriers by expanding insurance coverage and eliminating cost sharing, in most insurance plans, for preventive services."

— Arica White, Ph.D.

Two studies led by researchers at the U.S. Centers for Disease Control and Prevention (CDC) used the 2015 National Health Interview Survey to assess utilization of screening services in a nationally representative adult civilian population. Actual screening rates were compared to the estimated number who should be screened based upon recommendations from the U.S. Preventive Services Task Force or national targets from Healthy People 2020.

- **Colonoscopy:** In 2015, just under two-thirds of insured adults aged 50 to 75 years were screened for colorectal cancer within the recommended intervals. This is up substantially from the colonoscopy rate of 49.1 percent the CDC reported in 2010.

  In the second study, published March 3 in *Morbidity and Mortality Weekly Report (MMWR)*, the authors note the rate of colorectal cancer screening of 62.4 percent in 2015 is below the Healthy People 2020 target of 70.5 percent. Despite progress in increasing screening in many groups, low screening use was reported by persons without a usual source of health care (26.3 percent) and the uninsured (25.1 percent).

- **Pap Testing:** In 2015, more than 8 out of 10 insured women aged 21 to 65 years were screened for cervical cancer (83 percent) in accordance with recommendations. Cervical cancer screening test use was lowest (63.8 percent) among uninsured women.

  The screening rate for cervical cancer actually decreased slightly between 2000 and 2015 and remains below the target of 93.0 percent by 2020. However, the *MMWR* authors note that cervical cancer screening recommendations changed in 2012. The new extended screening intervals may have contributed to the slight decline in cervical cancer screening.

- **Glucose Testing:** In 2015, roughly two out of three overweight and obese insured adults aged 40 to 70 years had a fasting blood test for high blood sugar or diabetes in the past 12 months.

"The Affordable Care Act has helped to reduce such barriers by expanding insurance coverage and eliminating cost sharing, in most insurance plans, for preventive services," write the *MMWR* authors, led by Arica White, Ph.D., from the CDC's Division of Cancer Prevention and Control. "Persons without a usual source of health care and the uninsured had the lowest test use, with the overwhelming majority of the uninsured not up to date with breast and colorectal cancer screening."

Takeaway: The ACA is credited with increasing rates of some preventive health screening, although screening rates remain below Healthy People 2020 targets.

23andMe Receives FDA Approval for DTC Genetic Test

23andMe and the U.S. Food and Drug Administration (FDA) recently announced that the agency allowed marketing of 23andMe's Personal Genome Service Genetic Health Risk (GHR) tests for 10 diseases or conditions. "These are the first direct-to-consumer (DTC) tests authorized by the FDA that provide information on an individual's genetic predisposition to certain medical diseases or conditions, which may help to make decisions about lifestyle choices or to inform discussions with a health care professional," said the FDA in its statement.

> *"This is an important moment for people who want to know their genetic health risks and be more proactive about their health."*
>
> — Anne Wojcicki

In 2013, the FDA issued a warning letter to 23andMe requiring that it stop marketing its DTC Personal Genome Service. The FDA had concluded that the $99 saliva test was a class III medical device requiring FDA approval. But a little less than two years later, the company won FDA approval for a DTC genetic carrier test for Bloom Syndrome.

Now, the FDA has given 23andMe authority to market its DTC genetic testing report that indicates personal risk for certain diseases such as late-onset Alzheimer's, Parkinson's, and celiac. The approval was granted following de novo classification review—which can be used for low or moderate risk devices that are not substantially equivalent to existing devices. Tests reviewed under this approach will be subject to special controls regarding the test's "accuracy, reliability and clinical relevance." Future tests that are substantially equivalent to this DTC test will be able to utilize the 510(k) approval process.

"This is an important moment for people who want to know their genetic health risks and be more proactive about their health," declared 23andMe CEO and Co-founder Anne Wojcicki in a statement. "The FDA has embraced innovation and has empowered individuals by authorizing direct access to this information. It is a significant step forward for 23andMe and for the adoption of personal genetics."

Takeaway: After initially blocking DTC marketing of personal genome service, the FDA has granted approval for a 23andMe genetic health risk test.

GUIDELINES AT A GLANCE:

Testing Guidelines Address NGS, Cancer and Other Screenings

Guidelines at a Glance is a new feature from G2 Intelligence that surveys recent guidelines issued from the U.S. Preventive Services Task Force and diagnostics industry leaders such as the College of American Pathologists, the American Society for Clinical Pathology, Association for Molecular Pathology and others. You can review an archive of the guidelines covered in G2 publications at www.g2intelligence.com/guidelines. Here is a run down of some the most recent guidelines of interest to laboratories and pathologists.

Validation of Next-Generation Sequencing–Based Oncology Panels

A joint consensus recommendation of the Association for Molecular Pathology and College of American Pathologists published in the *Journal of Molecular Diagnostics* provides assistance to clinical laboratories with the validation and ongoing monitoring of next-generation sequencing-based testing for detection of somatic variants. The guideline seeks to ensure high quality of sequencing results of targeted gene panels and their diagnostic use in solid tumors and hematological malignancies.

Topics covered in the consensus recommendations include: next-generation sequencing-based test development, optimization, and validation. Specifically, it includes recommendations on panel content selection, utilization of reference materials for evaluation of assay performance, determining of positive percentage agreement and positive predictive value for each variant type, and requirements for minimal depth of coverage and minimum number of samples that should be used to establish test performance characteristics. The recommendations also discuss quality control metrics.

All women, regardless of ethnic background, should be offered expanded carrier screening prior to pregnancy, according to new recommendations published by the American College of Obstetricians and Gynecologists' Committee on Genetics.

Expanded Carrier Screening for All Women

All women, regardless of ethnic background, should be offered expanded carrier screening prior to pregnancy, according to new recommendations published by the American College of Obstetricians and Gynecologists' Committee on Genetics. Ethnic-specific screening, pan-ethnic screening, and expanded carrier screening are all "acceptable" strategies that can be used to identify the risk of genetic disorders in potential offspring. Additionally, the committee's recommendations say:

- Providers should establish "a standard approach that is consistently offered," although the ultimate screening approach for an individual should also be guided by the patient's family history and personal values.

GUIDELINES AT A GLANCE:

- Expanded carrier screening panels should include conditions that have a carrier frequency of 1 in 100 or greater, a well-defined phenotype, a detrimental effect on quality of life, cause cognitive or physical impairment, require surgical or medical intervention, or have an onset early in life.
- Regardless of ethnicity, screening strategy, or history, all patients should receive carrier screening for the following conditions: cystic fibrosis, spinal muscular atrophy, and thalassemias and hemoglobinopathies (plus a complete blood count).

Molecular Biomarkers for Colorectal Cancer

A joint guideline from the American Society for Clinical Pathology, College of American Pathologists, Association for Molecular Pathology, and American Society of Clinical Oncology, published in the March issue of the Journal of Molecular Diagnostics establishes evidence-based recommendations for mutational testing of EGFR signaling pathways for patients with colorectal cancer (CRC), as well as key steps laboratories can take to operationalize CRC molecular testing.

Laboratories must use validated CRC molecular biomarker testing methods with sufficient performance characteristics and must incorporate these methods into their overall laboratory quality improvement program.

A systematic literature review found evidence supporting mutational testing to guide therapy of CRC with anti-EGFR monoclonal antibodies. Mutations in BRAF and MMR have "clear prognostic value," while KRAS and NRAS have "relatively strong" evidence as negative predictors of benefit to anti-EGFR therapies. In addition to considerations for specific mutational analysis were recommendations for how laboratories can aid adoption of CRC molecular testing.

- Laboratories should use CRC molecular biomarker testing methods that are able to detect mutations with at least 5% mutant allele frequency.
- Laboratories should optimally utilize tissue specimens by using appropriate techniques (e.g., multiplexed assays).
- Laboratories must use validated CRC molecular biomarker testing methods with sufficient performance characteristics and must incorporate these methods into their overall laboratory quality improvement program.
- CRC molecular biomarker testing reports should include a results and interpretation section easily understandable by oncologists.
- It is suggested that 90% of reports be available within 10 working days from date of receipt in the molecular diagnostics laboratory.
- It is suggested that for laboratories requiring send-out testing, 90% of specimens should be sent out within 3 working days.

GUIDELINES AT A GLANCE:

> *"Based on the natural history of HSV infection, its epidemiology, and the available evidence on the accuracy of serologic screening tests, the USPSTF concluded that the harms outweigh the benefits of serologic screening for genital HSV infection."*
>
> — U.S. Preventive Services Task Force

Update for Screening for Genital Herpes

An update on screening for genital herpes remains "consistent" with the previous 2005 U.S. Preventive Services Task Force (USPSTF) recommendations against routine serologic screening for genital herpes simplex virus (HSV) infection in asymptomatic adolescents and adults. The update, published in the Dec. 20, 2016 issue of the *Journal of the American Medical Association*, includes the recommendation to not screen asymptomatic, pregnant women.

"Based on the natural history of HSV infection, its epidemiology, and the available evidence on the accuracy of serologic screening tests, the USPSTF concluded that the harms outweigh the benefits of serologic screening for genital HSV infection," the task force writes.

Evidence Lacking to Evaluate Celiac Screening

The U.S. Preventive Services Task Force (USPSTF) found there is not enough evidence to advocate for or against screening asymptomatic adults, adolescents, and children for celiac disease, according to the recommendation, published March 28 in the *Journal of the American Medical Association*. The standard method of diagnosing celiac disease in symptomatic patients (older than 2 years) is the tissue transglutaminase IgA test, followed by intestinal biopsy for histologic confirmation.

The finding includes a lack of evidence for targeted screening of those that are asymptomatic, but at high risk for the disease due to family history or other autoimmune disorders. USPSTF reports inadequate evidence regarding the accuracy, effectiveness, and benefits/harms of screening with regard to morbidity, mortality, or quality of life. USPSTF suggests the need for future studies, particularly in high-risk populations, that randomly assign participants to screening or no screening to evaluate clinical outcomes.

First Diagnostic Criteria Established for Castleman Disease

Castleman Disease is a rare, complex disease that often looks similar to a lymphoma, but can present like an autoimmune or infectious disorder. Diagnosis is complicated by a lack of a biomarker, leading to a recent push to establish diagnostic criteria (evidence-based consensus), which were recently published in *Blood*. The criteria require multicentric lymphadenopathy with defined histopathology, two or more clinical/laboratory changes (elevated CRP or ESR, anemia, thrombocytopenia, hypoalbuminemia, renal dysfunction, and/or polyclonal hypergammaglobulinemia), and exclusion of mimic conditions (infectious, autoimmune, or malignant).

Abbott and Alere Abandon Litigation and Reach New Terms for Acquisition

Abbott's deal to acquire Alere is back on. Both companies announced Friday, April 14, 2017, that they will move forward with the deal and have revised its terms. Abbott, a global health care company with a significant diagnostics business, had originally announced a plan to acquire Alere in February 2016. The parties were embroiled in lawsuits, however, after Alere became the subject of government subpoenas and Abbott sought to exit the deal. The formerly $5.8 billion transaction now is estimated to have a $5.3 billion equity value, with Abbott paying $51 per common share of Alere rather than the original $56 per share.

> *"The combination of Alere and Abbott will create the world's premier point of care testing business and significantly strengthen and grow Abbott's diagnostics presence."*
>
> — Miles D. White

At the time the deal was initially announced in 2016, Alere Chief Executive Officer Namal Nawana declared in a statement: "Our leading platforms and global presence in point-of-care diagnostics, combined with Abbott's broad portfolio of market-leading products, will accelerate our shared goal of improving patient care."

"The combination of Alere and Abbott will create the world's premier point of care testing business and significantly strengthen and grow Abbott's diagnostics presence," added Miles D. White, Abbott's chairman and chief executive officer in the same statement. "We want to offer our customers the best and broadest diagnostics solutions. Alere helps us do that."

Alere, which specializes in in vitro tests for influenza, hospital-acquired infections, toxicology and cardiology, received FDA 510(k) marketing clearance earlier this month for a rapid flu test for point of care and laboratory use. The Alere™ Reader "is the first rapid antigen influenza test to achieve 510(k) clearance as a Class II assay under the new FDA reclassification requirements," according to Alere's statement announcing the FDA approval. Additionally, the FDA is considering what would be the first approved POC HbA1c diagnostic test for diabetes in the US. Alere's Afinion HbA1c Dx would be considered a moderate-complexity test, i.e., labs would have to perform proficiency testing and follow other quality controls.

Before the acquisition can be completed, regulatory approvals will still need to be secured and Alere shareholders must approve the terms of the deal. If those approvals are secured, the deal is expected to be completed by the end of the third quarter in 2017. As part of the terms, both Abbott and Alere have agreed to drop their lawsuits against each other. You may recall that in December 2016, Abbott sought to have a Delaware Chancery Court let it out of the deal, claiming that Alere has lost "substantial value." Alere had filed litigation to move the deal forward and force Abbott to pursue regulatory filings needed for the deal. Earlier in 2016, Abbott had tried to negotiate an exit, offering Alere between $30 million and $50 million to call it off but Alere refused.

Takeaway: Abbott's planned acquisition of Alere will move forward after the parties have resolved litigation over whether to proceed with the deal.

Reports Indicate Faster FDA Approval Processes

The U.S. Food and Drug Administration (FDA) is plagued with chronic understaffing, scrutiny over the length of time for approvals, and an expanding workload, while also facing potential budget cuts proposed by the Trump administration. Yet, several recent reports are indicating improvements in the time to approval across drug and device types, which is welcome news to the life sciences industry.

Drug Approvals

For new therapeutic agents that were approved between 2011 and 2015, the regulatory reviews by the FDA were, on average, 60 days shorter than those by the European Medicines Agency (EMA), according to a correspondence published April 6 in the *New England Journal of Medicine*.

The authors say the speed of the U.S. regulatory review process will likely face scrutiny again, as Congress debates reauthorization of the Prescription Drug User Fee Act, which is set to expire this October. To inform this debate, the authors, led by Nicholas S. Downing, M.D., from Brigham and Women's Hospital in Boston, assessed all new therapeutic agents that had been approved by the FDA or the EMA between 2011 and 2015 and compared the median total review times between the agencies.

The researchers found that the FDA approved 170 new therapeutic agents over the four years, while the EMA approved 144. The FDA's median total review time was significantly shorter than the EMA's (306 days versus 383 days, respectively). Among the 142 therapeutic agents that were approved by agencies (with at least one of the approvals occurring during the study period), results were similar with median total review times of 303 days and 369 days, respectively.

"The FDA—like many other regulatory authorities—has become much more strict about clinical evidence and testing requirements, thus lengthening the overall path to clearance."

— Emergo Report

Device Approvals

Regulatory consultancy firm Emergo (Austin, Texas) recently released its 2017 report reviewing medical device applications submitted to the FDA from 2012 to 2016. While not exclusive to diagnostic products, the report offers some insights for the diagnostics industry.

In 2016, the number of devices that received 510(k) clearance fell to 2,957, the lowest number since 2010. The company says this decline in clearances is "entirely attributable" to fewer American companies submitting devices to the FDA. For products cleared by FDA internal review, it took, on average, 177 calendar days from submission to clearance in 2016.

"The FDA—like many other regulatory authorities—has become much more strict about clinical evidence and testing requirements, thus lengthening the overall path to clearance," Emergo writes in the report. "Most companies can plan on waiting about six months to get the green light from FDA, although that varies by device."

The report found that 58 percent of devices cleared in 2016 were cleared within six months of submission.

The results from both of these reports echo the FDA's own analysis. In recent testimony to the House Committee on Energy and Commerce regarding reauthorization of the Medical Device User Fee Amendments (MDUFA), Jeff Shuren, M.D., FDA's director of the Center for Devices and Radiological Health, credited the user fee program for reducing FDA decision times. He testified that the FDA has made "substantial progress" and said that in 2015 it took on average 133 days to reach a decision on a 510(k), an 11 percent decrease in five years.

Shuren also said that the FDA's workload continues to increase about 10 percent every year, in part because of the increasing complexity of innovative medical devices and because of the need to use real-world evidence in post-market surveillance. As a result of this increasing workload, even if the Trump administration's proposed cuts to regulation and staffing are made, the agency still needs the medical device user fees to continue to speed the review process.

Takeaway: Recent analyses shows the FDA is making progress to speed the regulatory review process across product types and the agency plans on continued need of user fees for continued improvements in review speed.

Discordant Results of Next Gen Tumor Profiling Raise Concerns

Conversations regarding oversight of diagnostic testing focus on the clinical and analytical validity of such testing and the ability to replicate results reliably. For example, the U.S. Food and Drug Administration's attempts to develop an oversight framework for laboratory developed testing focus on the reliability of these locally developed tests.

New technology and test methods raise the same concerns. Theranos first began facing troubles when reports claimed test results from Theranos' finger-stick testing methods differed from tests run using traditional testing platforms and methods.

A new study raises similar reliability questions based on discordant results involving next-generation sequencing (NGS), which has been touted as having significant promise. NGS is increasingly becoming commonplace, for example, to match cancer-associated alterations with targeted treatments. The FDA has held at least one workshop devoted to discussing potential standards for evaluating NGS and evidence of clinical performance and reliability. (See "*FDA Seeks Stakeholder Feedback on Evaluating Next-Generation Sequencing Tests*," *NIR*, March 24, 2015).

This study found that marked differences in results between two commercially available genetic tests for oncology patients may be "clinically relevant."

The research letter, published online Dec. 15, 2016 in *JAMA Oncology*, compared the tissue-based FoundationOne test (F1; Foundation Medicine) with the blood-based Guardant360 (G360; Guardant Health) test. F1 characterizes the exons of 315 cancer-associated genes and introns from 28 genes in-

volved in rearrangements, while G360 sequences 70 genes from cell-free circulating DNA. Previous published studies have shown that both the F1 and G360 tests have high specificities (above 99 percent), but lower sensitivities.

The present study compared results from both tests in nine patients seen at a community oncology practice. The level of concordance between the platforms was compared among the two men and seven women (mean age, 61 years). Testing occurred from April 14, 2015 to Jan. 30, 2016. In addition to comparing identified genomic alterations, test results were compared regarding recommended drugs.

"Since both the F1 and the G360 tests are performed in thousands of patients with cancer each year, these findings are clinically relevant. In-depth comparisons of next-generation sequencing tests across larger numbers of patients with cancer are needed to improve concordance and clinical utility."

— Nicole M. Kuderer, M.D.

The researchers found one patient had no identified genetic alterations using either test. Among the remaining eight patients, 45 alterations were identified, but only 10 alterations (22 percent) were concordant between the platforms. For two of the eight patients, there was no concordance among the reported alterations. Alterations that are unique to the F1 test, which detects a "much broader range" of aberrations than G360, were excluded from analysis. Concordance improved "only slightly" to 28 percent (5 of 18 alterations) when comparisons were limited to variant allele frequencies of 1 percent or greater.

For the eight patients with identified alterations, 36 drugs were recommended, in total. However, only one-quarter of the drugs were recommended for the same patients by both platforms. In five patients there was no overlap between the drugs recommended by the two tests. Concordance among recommended drugs improved to 62 percent (8 of 13 drugs), when reported mutations were also concordant.

In seeking an explanation for the discordant test results, the authors cite differences in timing between the two tests as a possible source, but note that seven of the eight patients with reported alterations underwent both tests within a 2.5-month period. Other potential sources of the discordance are tumor heterogeneity and differences in the variant-interpretation process.

"Since both the F1 and the G360 tests are performed in thousands of patients with cancer each year, these findings are clinically relevant," write the authors led by Nicole M. Kuderer, M.D., from University of Washington, Seattle. "In-depth comparisons of next-generation sequencing tests across larger numbers of patients with cancer are needed to improve concordance and clinical utility."

The authors note that theirs was not the first to identify "significant discordance." Two studies comparing tissue-based next-generation sequencing tests and another report also comparing the F1 and G360 tests, all found discordant test results.

Takeaway: Initial comparisons of commercially available next-generation sequencing tests to identify cancer-related variants targetable by therapies, raise concerns regarding the potential clinical relevance of discordant genetic findings and resulting drug recommendations.

FDA Reports "Significant Progress" in Diagnostics Development, *from page 1*

Advancing Health Promotion

The FDA supported the regulatory public health response to the threats of Ebola virus and Zika virus through development of tools, reference materials, and publication of guidance to support rapid development of new medical products to diagnose, treat, and prevent spread of these diseases.

Infrastructure Development

Over the past two years, the agency says it enhanced information technology tools that support scientific review of regulatory applications for complex, molecular diagnostics. To make possible the secure deposition, retrieval, and analysis of the vast data needed to support next-generation sequencing-based testing, the FDA continued to enhance its high-performance, scientific computing environments. Additionally, the FDA says it has expanded its ability to evaluate data from mass spectrometry for proteomics and glycomics.

Two other diagnostic-specific mentions in the report include the development of guidelines for reporting results of genetic tests in clinical pharmacology studies, as well as development of methods to analyze data from clinical validation studies for companion diagnostic assays.

Takeaway: Much of the progress the FDA notes in its recent report highlights how advances in diagnostic technology are driving advances in regulatory science.